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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,835	06/05/2006	Tor Kihlberg	PH0381	8539
36335 7590 05/13/2010 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231				
EXAMINER				
PERREIRA, MELISSA JEAN				
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1618				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/581,835

**Applicant(s)**

KIHLEBERG ET AL.

**Examiner**

MELISSA PERREIRA

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS/US)
- Paper No(s)/Mail Date 6/5/06

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-12 in the reply filed on 2/24/10 is acknowledged.
2. Claims 13-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/24/10.
3. The amendment to the instant claim 8 is not acknowledged at this time as an official amendment to the claims must be made of record.

### ***Drawings***

4. The drawings are objected to because the drawings contain FIG.6, FIG.6A and FIG.6B which is confusing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after

the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

5. The disclosure is objected to because of the following informalities: the specification recites, Fig.6 on pages 5 and 14 and does not recite Fig.6A or Fig.6B as stated in the drawings. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1 recites the limitation "the concave mirror". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) in view of Suzuki et al.

(EP0282703B1) and Shiba et al. (US 4,458,302) and in further view of Kihlberg et al. (US2004/0197257A1).

10. Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) discloses the production of high specific activity (no-carrier-added) [ $^{11}\text{C}$ ]phosgene wherein [ $^{11}\text{C}$ ]carbon monoxide was mixed with research purity chlorine flowing at 10 ml/min and the mixture was irradiated with an u.v.-lamp in a quartz spiral wound around the lamp to generate  $^{11}\text{COCl}_2$  which is collected in a reaction vessel after a period of time (p283, right column, especially experimental results; figure 1). The reaction apparatus comprises a first and a second gas inlet. Diksic et al. does not disclose a high pressure reaction chamber comprising a concave mirror or using a [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide enriched gas-mixture prepared via the method of the instant claim 2.

11. Suzuki et al. (EP0282703B1) discloses that UV radiation source which comprises a high pressure mercury vapor lamp, a concave mirror and a shutter which can be opened and closed wherein the radiant lights containing ultraviolet rays, which are emitted from the high pressure mercury lamp, are reflected by the concave mirror (column 4, lines 1-18).

12. Shiba et al. (US 4,458,302) discloses the use of concave mirrors for convergence of the light emitted from a Xe-Hg lamp (column 6, lines 3-10).

13. Kihlberg et al. (US2004/0197257A1) discloses the production of [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide enriched gas-mixture for labeling synthesis via a.) providing carbon-isotope dioxide in a suitable carrier gas (i.e. nitrogen, etc.); b.) converting carbon-isotope dioxide to carbon-isotope monoxide by introducing said gas mixture in a

reactor device; c.) trapping carbon-isotope monoxide in a carbon monoxide trapping device, wherein carbon-isotope monoxide is trapped but not said carrier gas; d.) releasing said trapped carbon-isotope monoxide from said trapping device in a well defined micro-plug, whereby a volume of carbon-isotope monoxide enriched gas-mixture is achieved (p2, [0018-0026]; claim 1).

14. Kihlberg et al. further teaches of the method of labeling synthesis wherein the method comprises a.) introducing the carbon-isotope monoxide (i.e. [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide) enriched gas-mixture into a reaction chamber, having a liquid reagent inlet and a labeling reactant inlet ([ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide); b.) introducing, at high pressure, the liquid reagent; c.) waiting a predetermined time while the labeling synthesis occurs; d.) removing the labeled liquid reagent from the reaction chamber. The step of waiting a predetermined time may further comprise heating the reaction chamber such that the labeling synthesis is enhanced (p2, [0031-0037]).

15. At the time of the invention it would have been obvious to one skilled in the art to substitute the UV radiation source which comprises a high pressure mercury vapor lamp, a concave mirror of Suzuki et al. for the UV assembly of Diksic et al. as the substitution of similar/comparable devices, wherein the technique is applicable to the base device, to generate the desired effect, such as converging all of the UV light to provide for the efficacious generation of  $^{11}\text{COCl}_2$ . It would be advantageous to one skilled in the art to utilize the UV radiation source of Suzuki et al. comprising a concave mirror to converge all of the light emitted from the UV source for a more efficient labeling synthesis.

16. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide enriched gas-mixture of Kihlberg et al. for the preparation of [ $^{11}\text{C}$ ]phosgene of Diksic et al. as it provides for the nearly quantitative conversion of the carbon-isotope monoxide into labeled products and the resulting labeled compound is highly concentrated (Kihlberg et al. p1, [0010],[0012]).

17. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the high pressure reaction chamber for the labeling synthesis/preparation of [ $^{11}\text{C}$ ]phosgene of Diksic et al. as the high pressures can increase reaction rates and minimize the amounts of reagents required (Kihlberg et al. p1, [0007]) and both disclosures are drawn to the method of labeling synthesis utilizing [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide.

18. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kihlberg et al. (US 7,521,544B2) in view of Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, *9*, 283-285).

19. Kihlberg et al. (US7,521,544B2) discloses the method of labeling synthesis comprising a UV reactor assembly comprising a high pressure reaction chamber, a UV lamp and a concave mirror. The method involves providing a reagent volume to be labeled, introducing a [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ] carbon-isotope monoxide enriched gas-mixture into the UV reactor via a gas inlet and the reagent volume to be labeled via a liquid inlet, turning on the UV lamp and waiting a predetermined time for the labeling synthesis and removing the labeled product (claim 1; column 3, lines 6-40).

20. The carbon-isotope monoxide enriched gas mixture is produced by a.) providing carbon-isotope dioxide in a suitable carrier gas (i.e. nitrogen, etc.); b.) converting carbon-isotope dioxide to carbon-isotope monoxide by introducing said gas mixture in a reactor device; c.) trapping carbon-isotope monoxide in a carbon monoxide trapping device, wherein carbon-isotope monoxide is trapped but not said carrier gas; d.) releasing said trapped carbon-isotope monoxide from said trapping device in a well defined micro-plug, whereby a volume of carbon-isotope monoxide enriched gas-mixture is achieved (claims 2-4; column 4, lines 14-42). The step of waiting a predetermined time comprises stirring the reaction chamber or adjusting the temperature of the reaction chamber to enhance the labeling synthesis (claims 6 and 7). Figure 3 shows the UV reactor assembly which comprises a motor, magnetic stirrer, sapphire window, bench and protective housing (fig.3 and 5; column 7, lines 41-48; column 8, lines 31-43). Kihlberg et al. does not disclose the labeling synthesis of phosgene.

21. Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) discloses the production of high specific activity (no-carrier-added) [ $^{11}\text{C}$ ]phosgene wherein [ $^{11}\text{C}$ ]carbon monoxide was mixed with research purity chlorine flowing at 10 ml/min as well as that stated above.

22. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the method of labeling synthesis of Kihlberg et al. for the preparation of [ $^{11}\text{C}$ ]phosgene of Diksic et al. as the resulting labeled compound is highly concentrated



and the method of Kihlberg et al. provides for an enhanced radiochemical yield (Kihlberg et al. column 4, lines 5-9; column 17, lines 56+; table 2).

### ***Double Patenting***

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,521,544 in view of Diksic et al. (*Int. J. Nucl. Med. Biol.* **1982**, 9, 283-285) because the method of labeling synthesis of the instant claims encompasses the method for labeling synthesis of 7,521,544 as they use the same UV reactor assembly, high pressure reaction chamber and carbon-isotope monoxide enriched gas-mixture prepared by the same method to label a reagent volume. U.S. Patent No. 7,521,544 does not disclose that the reagent volume to be labeled is phosgene via mixing carbon-isotope monoxide enriched gas-mixture with chlorine gas.

25. Diksic et al. discloses the preparation of [ $^{11}\text{C}$ ]phosgene via mixing [ $^{11}\text{C}$ ]carbon monoxide with research purity chlorine and irradiation with an u.v.-lamp.

26. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the method of labeling synthesis of 7,521,544, such as the use of the [ $^{11}\text{C}$ ,  $^{13}\text{C}$ ,  $^{14}\text{C}$ ]carbon monoxide enriched gas-mixture of 7,521,544 for the preparation of [ $^{11}\text{C}$ ]phosgene of Diksic et al. as the resulting labeled compound is highly concentrated and the method of 7,521,544 provides for an enhanced radiochemical yield (7,521,544 column 4, lines 5-9; column 17, lines 56+; table 2).

27. Claims 8-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of copending Application No. 12/423,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the system for labeling synthesis of the instant claims comprising a UV reactor assembly comprising a high pressure reaction chamber, UV lamp, motor, magnet, magnetic stirring bar, concave mirror, sapphire window, protective housing, etc. of the instant claims encompasses the system for labeling synthesis of application 12/423,034 as it comprises the same components. The high pressure reaction chamber of the instant claims has a first gas inlet and a second gas inlet while the high pressure reaction chamber of the copending application 12/423,034 has a liquid inlet and a gas inlet and it would have been obvious to one skilled in the art that the liquid inlet of the high pressure reaction chamber can be adapted for the intake of gas.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

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